

Response dated 04/29/2005
Response to Office Action mailed 07/02/2004

Application No. 10/044,405

REMARKS

A petition to revive along with the fee is included with this filing. Claims 1-4 and 6-23 stand rejected, and claims 1-17 and 21-23 stand objected due to certain informalities. By this response, claims 1, 5-7, 10-13, 15-18 have been amended and claim 14 has been canceled. No new matter has been introduced into the application. As explained in more detail below, Applicant submits that all pending claims are in condition for allowance and respectfully requests such notification.

Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant would like to thank the Examiner for indicating allowable subject matter. Applicant has amended claim 5 to include the features of the base claim and all intervening claims from which claim 5 depends. Therefore, Applicant respectfully submits that claim 5 is in condition for allowance.

Claim Objections

In the Office Action, claims 1-17 and 21-23 were objected to because of certain informalities.

Applicants have amended claims 1, 5-7, 10-13, and 15-18 in order to more particularly point out and distinctly claim features of Applicant's invention. The amendments are in line with the Office Action's suggestions. Therefore, Applicant respectfully requests withdrawal of the rejection.

Information Disclosure Statement

The information disclosure statement filed 12/30/03 fails to comply with 37 CFR §1.98(a)(3) because it does not include a concise explanation of the relevance . . . of each patent (FR 2500309) that is not in the English language.

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With this response, Applicant has submitted a supplemental information disclosure statement and fee along with an English abstract of FR 2500309.

Claim Rejections Under 35 USC §102

Claims 1, 2, 5-15 and 17-23 are rejected under 35 USC §102(e) as being anticipated by Gliner, U.S. Publication No. 2002/0055762.

Gliner discloses delivering percutaneous or transcutaneous electrical nerve stimulation to a patient. Each electrode can include a probe such as a needle, which may be inserted into the patient's tissue. Alternatively, each electrode can include a surface-mounted patch for transcutaneous therapy. The frequency of electrical pulses for the stimulation may be varied according to a schedule or function of time.

Independent claims 1, 10, 13, and 18 have been amended to remove certain formalities described in the current Office Action. In regard to independent claims 1 and 10 Applicant respectfully submits that Gliner does not disclose, teach, or suggest at least the claimed feature of "changing a value of a second of the stimulation parameters based upon having pseudo-randomly varied the first stimulation parameter", much less doing so "based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter." In contrast, Gliner merely discloses adjusting frequency based upon a schedule within a particular frequency range. For instance, Gliner states in paragraph [0061]:

FIG. 12 is a flow diagram of a process 1210 for automatically varying the frequency with which electrical pulses are delivered to a recipient. In 1212, the process can include receiving a schedule for varying the frequency. The schedule can include a minimum frequency value, a maximum frequency value, pulse durations and/or IPIs for each frequency, a period over which the frequency changes from the minimum value to a maximum value and back, and a rate at which the frequency changes from the minimum value to the maximum value and back.

(Emphasis Added). As stated above, Gliner merely discloses adjusting the frequency based upon a time schedule. Gliner does not disclose, teach, or suggest "changing a value of a second of the stimulation parameters based upon having pseudo-randomly varied the first stimulation parameter", much less do so "based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter." As

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illustrated in at least Figure 4 of Applicant's specification, the predetermined relationship may, for example, be a strength-duration curve for neural excitation determined for individual neurons or population of neurons. The exemplary curve of Figure 4 may be a function of the stimulation current level and pulse duration required for excitation of one or more neurons. The strength-duration relationship may be determined clinically by:

measuring the required stimulus current at various pulse durations to achieve some clinical outcome measure (e.g., reduction of tremor with thalamic stimulation). Once this relationship has been measured for a given electrode (or combination of electrodes) in a given patient, these data can be used to generate random or pseudo-random combinations of amplitude and pulse width values that have been determined to provide the desired clinical outcome.

(Specification, Paragraph 30).

The adjusting of frequency on a time schedule as describe in Gliner does not disclose, teach, or suggest "changing a value of a second of the stimulation parameters . . . based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter." Independent claims 13 and 18 each contain a similar claimed feature as those discussed above in relation to independent claims 1 and 10. Therefore, for at least this reason, Applicant respectfully submits that independent claims 1, 10, 13, and 18 are in condition for allowance. Claims 2-4, 6-9, 11-12, 15-17, and 19-23 which ultimately depend from one of the above independent claims are allowable for at least the same reason as the independent claim from which they depend.

In addition, independent claim 10 is allowable for at least an additional reason. Independent claim 10 has been amended to claim the feature of "providing deep brain neural stimulation" (Emphasis Added). Applicant respectfully submits that Gliner does not disclose, teach, or suggest this claimed feature. Therefore, Applicant submits that independent claim 10 is allowable over the cited documents for at least this additional reason. Dependent claims 11 and 12, which depend from independent claim 10, are allowable for at least the same reason.

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Claim Rejections Under 35 USC §103

Claims 3 and 4 are rejected under 35 USC §103(a) as being unpatentable over Gliner.

Dependent claims 3 and 4 ultimately depend from independent claim 1 and are allowable for at least the same reasons as independent claim 1.

In addition, claims 3 and 4 are allowable for at least an additional reason. The Office Action states:

Gliner discloses the claimed invention except for measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neural stimulation system/method as taught by Gliner, with a measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved since it was known in the art that neural stimulation system/methods have steps for measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved in order to maintain the stimulation capability of the electrical stimulation pulses substantially constant to provide a desired outcome.

(Office Action, Page 4).

Applicant agrees with the Office Action that Gliner does not disclose measuring of the patient's neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved. Applicant, however, respectfully disagrees with the Office Action's assertion regarding knowledge available in the art. In particular, the Office Action does not provide any support showing that it was known in the art to measure the strength-duration curve for neural excitation for at least one of a patient's neurons for the use as a predetermined relationship to change a value of a second of the stimulation parameters based upon having pseudo-randomly varied a first stimulation parameter. The cited documents (Gliner and Mouine) do not disclose a predetermined relationship as claimed. Therefore, for at least this additional reason, Applicant respectfully submits that dependent claims 3 and 4 are in condition for allowance.

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Claim Rejections Under 35 USC §102 and §103

Claims 1 and 8-23 are rejected under 35 USC §102(e) as being anticipated by or, in the alternative, under 35 USC 103(a) as being obvious over Mouine, et al, U.S. Publication No. 2004/102820.

Mouine discloses a programmable neurostimulator for urinary control. A user interface enables programming stimulation algorithms through a communications link. The algorithm described in Mouine uses:

an electrical train of pulses of random amplitude and/or frequency and/or width by interval, while keeping a predetermined average. In fact, these parameters define the amount of charges that are delivered to the nerve. By so varying them, a way is provided to prevent the nerve from getting accustomed, and thus less responsive, to the specific electrical stimulation.

(Mouine, Paragraph 0049).

Independent claims 1, 10, 13, and 18 have been amended to remove certain formalities described in the current Office Action. Similar to the above remarks regarding Glines, Applicant respectfully submits that Mouine does not disclose, teach, or suggest the claimed features of "changing a value of a second of the stimulation parameters based upon having pseudo-randomly varied the first stimulation parameter", much less doing so "based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter." In contrast, Mouine merely discloses randomly or progressively varying/adjusting frequency and amplitude while keeping a predetermined average. (Mouine, Paragraph 0051). Mouine does not disclose, teach, or suggest "changing a value of a second of the stimulation parameters . . . based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter." Therefore, for at least this reason, Applicant respectfully submits that independent claims 1, 10, 13, and 18 are in condition for allowance. Claims 2-4, 6-9, 11-12, 15-17, and 19-23 which ultimately depend from one of the above independent claims are allowable for at least the same reason as the independent claim from which they depend.

The Office Action, in the alternative further rejects claims 1 and 8-23 under 35 USC §103(a). In particular, the Office Action on page 5 states:

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In the alternative, Mouine discloses the claimed invention except for the changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how a first parameter affects desirable values for the second parameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neurostimulation system/method as taught by Mouine, with a changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter since it was known in the art that neurostimulation systems use a changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter to maintain the simulation capability of the simulation pulses substantially constant to provide therapy to the patient.

Applicant agrees with the Office Action's statement that Mouine does not disclose "changing a value of a second of the stimulation parameters based upon having pseudo-randomly varied the first stimulation parameter and based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter." However, Applicants respectfully disagree with the Office Action's assertion regarding knowledge available in the art. In particular, the Office Action does not provide any support showing that it was known in the art to change a second stimulation parameter based on a predetermined relationship between how changes in the first parameter affect desirable values for the second parameter. The cited documents (Gliner & Mouine) do not disclose, teach, or suggest this claimed feature. If the Examiner is relying on personal knowledge, it is respectfully requested that this be indicated in the rejection. Therefore, for at least this reason, Applicant respectfully submits that independent claims 1, 10, 13, and 18 are in condition for allowance. Claims 2-4, 6-9, 11-12, 15-17, and 19-23 which ultimately depend from one of the above independent claims are allowable for at least the same reason as the independent claim from which they depend.

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Applicant respectfully submits that pending claims are in condition for allowance. A notice to this effect is respectfully requested. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

Respectfully submitted,

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